

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ACTELION PHARMACEUTICALS US,
INC., ACTELION PHARMACEUTICALS
LTD and NIPPON SHINYAKU CO., LTD.,

Plaintiffs,

v.

ALEMBIC PHARMACEUTICALS LIMITED
and ALEMBIC PHARMACEUTICALS, INC.,

Defendants.

C.A. No.: 22-1450-GBW
(consolidated)

SCHEDULING ORDER

This 10th day of July, 2023, the Court having conducted an initial Rule 16(b)

scheduling conference pursuant to Local Rule 16.1(b), and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;

IT IS HEREBY ORDERED that:

1. Rule 26(a)(1) Initial Disclosures and E-Discovery Default Standard.

Unless otherwise agreed to by the parties, the parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) within seven (7) business days of the date this Order is entered by the Court. If they have not already done so, the parties are to review the Court's Default Standard for Discovery, Including Discovery of Electronically Stored Information ("ESI"), which is posted at <http://www.ded.uscourts.gov> (see Other Resources, Default Standard for Discovery) and is incorporated herein by reference.

2. Joinder of Other Parties and Amendment of Pleadings. All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before January 16, 2024.

Unless otherwise ordered by the Court, any motion to join a party or motion to amend the pleadings shall be made pursuant to the procedures set forth in Paragraphs 3(g) and 4.

3. Discovery. Unless otherwise ordered by the Court or agreed to by parties, the limitations on discovery set forth in the Federal Rules of Civil Procedure shall be strictly observed.

(a) Fact Discovery Cut Off. All fact discovery in this case shall be initiated so that it will be completed on or before February 29, 2024.

(b) Document Production. Document production shall be substantially complete by November 14, 2023.

(c) Requests for Admission. Defendants may serve up to 10 joint requests for admission on Plaintiffs. In addition, each Defendant family¹ may serve up to 10 individual requests for admission on Plaintiffs. Plaintiffs may serve up to 10 joint requests for admission on Defendants, which each Defendant family may answer individually. In addition, Plaintiffs may serve up to 10 individual requests for admission on each Defendant family.

(d) Interrogatories.

i. Defendants may serve up to 15 joint interrogatories, including contention interrogatories, on Plaintiffs. In addition, each Defendant family may serve up to 5 individual interrogatories, including contention interrogatories, on Plaintiffs. Plaintiffs may serve up to 15 joint interrogatories, including contention interrogatories, on Defendants, which each Defendant family may answer individually. In addition, Plaintiffs may serve up to 5 interrogatories, including contention interrogatories, on each Defendant family.

¹ There are three Defendant families in this matter: (1) Alembic, (2) Lupin, and (3) Cipla.

ii. The Court encourages the parties to serve and respond to contention interrogatories early in the case. In the absence of agreement among the parties, contention interrogatories, if filed, shall first be addressed by the party with the burden of proof. The adequacy of all interrogatory answers shall be judged by the level of detail each party provides (*i.e.*, the more detail a party provides, the more detail a party shall receive).

(e) Depositions.

i. Limitation on Hours for Deposition Discovery. Each side is limited to a total of 70 hours of taking fact witness testimony by deposition upon oral examination and no more than 10 depositions per side, including third-party depositions under Federal Rule of Civil Procedure 45 and depositions noticed under Federal Rule of Civil Procedure 30(b)(6). Each party will attempt in good faith to minimize the number of witnesses for depositions noticed under Federal Rule of Civil Procedure 30(b)(6), but regardless each deposition noticed under Federal Rule of Civil Procedure 30(b)(6) will count as a single deposition for the purpose of the 10 deposition per side limit no matter how many witnesses are designated in response.

ii. Location of Depositions. Any party or representative (officer, director, or managing agent) of a party filing a civil action in this district court must ordinarily be required, upon request, to submit to a deposition at a place designated within this district. Exceptions to this general rule may be made by agreement of the parties or by order of the Court, including with respect to the use of remote depositions. A defendant who becomes a counterclaimant, cross-claimant, or third-party plaintiff shall be considered as having filed an action in this Court for the purpose of this provision.²

² The Parties will confer in good faith regarding counsel accepting service of deposition notices on behalf of current and former employees whom they will be representing at deposition.

(f) Disclosure of Expert Testimony.

i. Expert Reports. For the party who has the initial burden of proof on the subject matter, the initial Federal Rule of Civil Procedure 26(a)(2) disclosure of expert testimony is due on or before March 28, 2024. The supplemental disclosure to contradict or rebut evidence, including initial disclosures of objective indicia of nonobviousness, on the same matter identified by another party is due on or before April 30, 2024. Reply expert reports from the party with the initial burden of proof, including to rebut or contradict initial disclosures of objective indicia of nonobviousness, are due on or before May 30, 2024. No other expert reports will be permitted without either the consent of all parties or leave of the Court. Along with the submissions of the expert reports, the parties shall advise of the dates and times of their experts' availability for deposition.

ii. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later than fourteen (14) days after the close of expert discovery, unless otherwise ordered by the Court. Briefing will be presented pursuant to the Court's Local Rules.

iii. Expert Discovery Cut Off. All expert discovery in this case shall be initiated so that it will be completed on or before July 2, 2024.

(g) Discovery Matters and Disputes Relating to Protective Orders.

i. Any discovery motion filed without first complying with the following procedures will be denied without prejudice to renew pursuant to these procedures.

ii. Should counsel find, after good faith efforts - including verbal communications among Delaware and Lead Counsel for all parties to the dispute - that they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall submit a joint letter in substantially the following form:

Dear Judge Williams:

The parties in the above-referenced matter write to request the scheduling of a discovery teleconference.

The following attorneys, including at least one Delaware Counsel and at least one Lead Counsel per party, participated in a verbal meet-and-confer (in person and/or by telephone) on the following date(s): _____

Delaware Counsel: _____

Lead Counsel: _____

The disputes requiring judicial attention are listed below:

[provide here a non-argumentative list of disputes requiring judicial attention]

iii. On a date to be set by separate order, generally not less than forty-eight (48) hours prior to the conference, the party seeking relief shall file with the Court a letter, not to exceed three (3) pages, outlining the issues in dispute and its position on those issues. On a date to be set by separate order, but generally not less than twenty-four (24) hours prior to the conference, any party opposing the application for relief may file a letter, not to exceed three (3) pages, outlining that party's reasons for its opposition.

iv. Each party shall submit two (2) courtesy copies of its discovery letter and any attachments.

v. Should the Court find further briefing necessary upon conclusion of the telephone conference, the Court will order it. Alternatively, the Court may choose to resolve the dispute prior to the telephone conference and will, in that event, cancel the conference.

4. Motions to Amend.

(a) Any motion to amend (including a motion for leave to amend) a pleading shall **NOT** be accompanied by an opening brief but shall, instead, be accompanied by a letter, not to exceed three (3) pages, describing the basis for the requested relief, and shall attach the proposed amended pleading as well as a “blackline” comparison to the prior pleading.

(b) Within seven (7) days after the filing of a motion in compliance with this Order, any party opposing such a motion shall file a responsive letter, not to exceed five (5) pages.

(c) Within three (3) days thereafter, the moving party may file a reply letter, not to exceed two (2) pages, and, by this same date, the parties shall file a letter requesting a teleconference to address the motion to amend.

5. Motions to Strike.

(a) Any motion to strike any pleading or other document shall **NOT** be accompanied by an opening brief but shall, instead, be accompanied by a letter, not to exceed three (3) pages, describing the basis for the requested relief, and shall attach the document to be stricken.

(b) Within seven (7) days after the filing of a motion in compliance with this Order, any party opposing such a motion shall file a responsive letter, not to exceed five (5) pages.

(c) Within three (3) days thereafter, the moving party may file a reply letter, not to exceed two (2) pages, and, by this same date, the parties shall file a letter requesting a teleconference to address the motion to strike.

6. Technology Tutorials. Unless otherwise ordered by the Court, the parties jointly shall provide the Court, no later than the date on which the Joint Claim Construction Chart is due, a tutorial on the technology at issue. In that regard, the parties shall jointly submit to the Court an electronic tutorial of not more than thirty (30) minutes. The tutorial should focus on the technology in issue and educate the Court about the same and should not be used for argument. As to the format selected, the parties should confirm the Court's technical abilities to access the information contained in the tutorial ("mpeg", "quicktime", etc.). The parties may choose to file their tutorial under seal, subject to any protective order in effect.

7. Claim Construction Issue Identification. On or before September 6, 2023, the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction of those term(s)/phrase(s). On or before September 13, 2023, the parties shall respond to and provide their proposed construction for any term(s)/phrase(s) presented by the other side for which the party did not initially provide a construction. These documents will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be filed no later than September 29, 2023. The Joint Claim Construction Chart, in Word format shall be e-mailed simultaneously with filing to gbw_civil@ded.uscourts.gov. The parties' Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue, and should include each party's proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. A

copy of the patent(s) in issue as well as those portions of the intrinsic record relied upon shall be submitted with this Joint Claim Construction Chart. In this joint submission, the parties shall not provide argument.

8. Claim Construction Briefing. Plaintiffs shall serve, but not file, their opening brief, not to exceed 5,000 words, on October 26, 2023. Defendants shall serve, but not file, their answering brief not to exceed 7,500 words, on November 30, 2023. Plaintiffs shall serve, but not file, their reply brief, not to exceed 5,000 words, on December 21, 2023. Defendants shall serve, but not file their sur-reply brief, not to exceed 2,500 words, on January 11, 2024. No later than January 17, 2024, the parties shall file a Joint Claim Construction Brief. The parties shall copy and paste their unfiled briefs into one brief, with their positions on each claim term in sequential order, in substantially the form below.

JOINT CLAIM CONSTRUCTION BRIEF

I. Agreed-Upon Constructions

II. Disputed Constructions

[TERM 1]

1. Plaintiffs' Opening Position
2. Defendants' Answering Position
3. Plaintiffs' Reply Position
4. Defendants' Sur-Reply Position

[TERM 2]

1. Plaintiffs' Opening Position
2. Defendants' Answering Position
3. Plaintiffs' Reply Position
4. Defendants' Sur-Reply Position

If there are any materials that would be submitted in an index, the parties shall submit them in a Joint Appendix.

9. Hearing on Claim Construction. Beginning at 1:00 p.m. on February 1, 2024 the Court will hear argument on claim construction. The parties shall notify the Court, by joint letter submission, no later than the date on which their answering claim construction briefs are due: (i) whether they request leave to present testimony at the hearing; and (ii) the amount of time they are requesting be allocated to them for the hearing.

Provided that the parties comply with all portions of this Scheduling Order, and any other orders of the Court, the parties should anticipate that the Court will issue its claim construction order within sixty (60) days of the conclusion of the claim construction hearing. If the Court is unable to meet this goal, it will advise the parties no later than sixty (60) days after the conclusion of the claim construction hearing.

10. Interim Status Report. On February 22, 2024, counsel shall submit a joint letter to the Court with an interim report of the matters in issue and the progress of discovery to date. Thereafter, if the Court deems it necessary, it will schedule a status conference.

11. Supplementation. Absent agreement among the parties, and approval of the Court,

(a) no later than February 8, 2024, the patentee must finally supplement the identification of all accused products and serve final infringement contentions; and

(b) no later than February 15, 2024, the accused infringers must finally supplement the identification of all invalidity references and serve final invalidity contentions.

12. Case Dispositive Motions. Absent agreement between the parties, and prior approval from the Court, the Court will not hear case dispositive motions in ANDA cases.

13. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion filed with the Clerk. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

14. Motions in Limine. Motions *in limine* shall not be separately filed. All *in limine* requests and responses thereto shall be set forth in the proposed pretrial order. Each *SIDE* shall be limited to three (3) *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of three (3) pages of argument, may be opposed by a maximum of three (3) pages of argument, and the side making the *in limine* request may add a maximum of one (1) additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three (3) page submission (and, if the moving party, a single one (1) page reply), unless otherwise ordered by the Court. No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

15. Pretrial Conference. On January 21, 2025, the Court will hold a pretrial conference in Court with counsel beginning at 1:00 p.m. Unless otherwise ordered by the Court, the parties should assume that filing the pretrial order satisfies the pretrial disclosure requirement of Federal Rule of Civil Procedure 26(a)(3). The parties shall file with the Court the joint proposed final pretrial order in compliance with Local Rule 16.3(c) and the Court's Preferences and Procedures for Civil Cases not later than seven (7) days before the

pretrial conference. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d)(1)-(3) for the preparation of the joint proposed final pretrial order.

The parties shall provide the Court two (2) courtesy copies of the joint proposed final pretrial order and all attachments. The proposed final pretrial order shall contain a table of contents and the paragraphs shall be numbered.

16. Application to Court for Protective Order. Should counsel find it will be necessary to apply to the Court for a protective order specifying terms and conditions for the disclosure of confidential information, counsel should confer and attempt to reach an agreement on a proposed form of order and submit it to the Court within ten (10) days from the date the Court enters this Order. Should counsel be unable to reach an agreement on a proposed form of order, counsel must follow the provisions of Paragraph 3(g) above.

Any proposed protective order must include the following paragraph:

Other Proceedings. By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated "confidential" [the parties should list any other level of designation, such as "highly confidential," which may be provided for in the protective order] pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

17. Papers Filed Under Seal. In accordance with section G of the Revised Administrative Procedures Governing Filing and Service by Electronic Means, a redacted version of any sealed document shall be filed electronically within seven (7) days of the filing of the sealed document.

18. Courtesy Copies. The parties shall provide to the Court two (2) courtesy copies of filings (i.e., briefs, appendices, exhibits, declarations, affidavits etc.). Courtesy copies of appendices and exhibits should include hard tabs. This provision also applies to papers filed under seal.

19. ADR Process. This matter is referred to a magistrate judge to explore the possibility of alternative dispute resolution.

20. Trial. This matter is scheduled for a five day bench trial beginning at 9:30 a.m. on January 27, 2025, with the subsequent trial days beginning at 9:30 a.m. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.

21. Post-Trial Briefing. The parties will address the post-trial briefing schedule and page limits in the proposed final pretrial order.



The Honorable Judge Gregory B. Williams
United States District Judge

Counsel Shall Provide a Chart of All Relevant Deadlines

EVENT	DATE
Exchange Initial Disclosures Pursuant to Federal Rule of Civil Procedure 26(a)(1)	Within 7 business days of entry of this Order
Proposed Discovery Confidentiality Order	May 15, 2023 M
Plaintiffs' Disclosure of Accused Products, Asserted Claims, and Production of File Histories	June 1, 2023 Th
Initial Disclosures Pursuant to Default Standard for Discovery, Including Discovery of Electronic Stored Information	June 1, 2023 Th
Defendants' Production of Core Technical Documents	June 30, 2023 F
Plaintiffs' Production of Initial Claim Charts	July 31, 2023 M
Defendants' Initial Invalidity Contentions and Accompanying Productions	August 30, 2023 W
Exchange Claim Terms to be Construed and Proposed Constructions	September 6, 2023 W
Responsive Exchange of Claim Terms to be Construed and Proposed Constructions	September 13, 2023 W
Joint Claim Construction Chart and any Technology Tutorials Filed with the Court	September 29, 2023 F
Plaintiffs Serve Opening <i>Markman</i> Brief	October 26, 2023 Th
Substantial Completion of Document Production	November 14, 2023 T
Defendants Serve Responsive <i>Markman</i> Brief	November 30, 2023 Th
Plaintiffs Serve Reply <i>Markman</i> Brief	December 21, 2023 Th
Defendants Serve Sur-reply <i>Markman</i> Brief	January 11, 2024 Th

EVENT	DATE
Deadline to Amend Pleadings or Join Parties	January 16, 2024 T
Parties to file Joint Claim Construction Brief	January 17, 2024 W
Claim Construction Hearing	February 1, 2024 Th
Plaintiffs Provide Final Supplement Indicating Accused Products and Serve Final Infringement Contentions	February 8, 2024 Th
Defendants Provide Final Supplement Identifying All Invalidity References and Serve Final Invalidity Contentions	February 15, 2024 Th
Interim Status Report	February 22, 2024 Th
Close of Fact Discovery	February 29, 2024 Th
Exchange Opening Expert Reports on Issues for Which Party Bears Burden of Proof	March 28, 2024 Th
Exchange Responsive Expert Reports (Including Plaintiffs' Objective Indicia of Non-Obviousness)	April 30, 2024 T
Exchange Reply Expert Reports	May 30, 2024 Th
Close of Expert Discovery	July 2, 2024 T
Objections to Expert Testimony	July 16, 2024 T
Plaintiffs provide draft Pretrial Order to Defendants	August 26, 2024 M
Defendants to provide responses to Plaintiffs' draft Pretrial Order	September 10, 2024 T

EVENT	DATE
Parties to File Joint Proposed Final Pretrial Order	January 14, 2025 T
Final Pretrial Conference	January 21, 2025 T
Trial	January 27, 2025 M
End of 30-Month Automatic Stay for Alembic's approval	March 29, 2025
End of 30-Month Automatic Stay for Lupin's approval	July 5, 2025
End of 30-Month Automatic Stay for Cipla's approval	September 13, 2025